Health Canada Santé Canada

Graham Spry Building
250 Lanark Avenue
A.L. 2005D
Ottawa ON K1A 0K9

07-100154-75

Provincial and Territorial Deputy Ministers of Health
Provincial and Territorial Drug Program Managers
Deans of Pharmacy
Registrars of Provincial Medical and Pharmacy Associations
Industry and Consumer Associations
Regulatory and Health Professional Associations
Other Interested Parties

Dear Sir/Madam:

Re: *Food and Drug Regulations* - Project # 1541 - Schedule F

This Notice of Intent (NOI) is to provide an opportunity for comment on the proposal to amend Part I of Schedule F to the *Food and Drug Regulations* to provide an exemption to allow nonprescription status for diclofenac and its salts when sold as a single medicinal ingredient in a concentration equivalent to 1% or less diclofenac in preparations for topical use on the skin.

Schedule F is a list of medicinal ingredients, the sale of which is controlled under sections C.01.041 to C.01.049 of the *Food and Drug Regulations*. Part I of Schedule F lists ingredients that require a prescription for human use and for veterinary use. Part II of Schedule F lists ingredients that require a prescription for human use, but do not require a prescription for veterinary use if so labelled or if in a form unsuitable for human use.

Diclofenac and its salts is a non-steroidal anti-inflammatory analgesic drug (NSAID) that is available in Canada as a prescription drug to reduce inflammation and pain in conditions such as arthritis, acute injury and kidney stones. Prescription drug products containing diclofenac are available as oral dosage forms, suppositories and topical products containing more than 1% diclofenac.

Diclofenac as a 1% topical preparation is intended to be applied to the skin for the relief of pain due to muscle and joint injuries such as sprains, strains and sports injuries. Although there is currently no diclofenac 1% topical product on the market in Canada, it has been approved for marketing in over 100 countries world-wide since 1985.

.../2

A nonprescription 1% topical strength would provide a route and dose option to those who wish to use a topical treatment for the acute pain of a sprain or strain type injury to a muscle or joint. It is not intended for use in conjunction with oral pain medications but rather as a stand-alone treatment. The product labelling will address this condition of use. The use of a topical NSAID rather than an oral product is a valid consideration and approach to treating such localized complaints as it minimizes the side effects associated with systemic NSAIDs. The product should be applied 3 to 4 times a day.The duration of use should not exceed 7 days of continuous treatment without consulting a practitioner.

Post-marketing experience indicates that the 1% dosage strength of diclofenac for topical use is not associated with significant adverse effects. There are no dose-related or age-related adverse effects and no special population is at risk. The likelihood of diclofenac use masking the symptoms of a serious condition is very low. In addition to its large safety margin, side effects are minor and transient in nature. The use of the nonprescription product in other countries has revealed no indication that the drug product poses generalized safety problems that would be incompatible with self-care use by Canadians.

Alternatives

The alternative option would be to leave diclofenac and its salts on Schedule F without any exemption for 1% or less concentrations for topical use on the skin. As measured against the factors for listing drugs on Schedule F, it has been determined that maintaining diclofenac and its salts on Schedule F without any exemption is not appropriate. The availability of a nonprescription 1% diclofenac for topical use would provide a treatment option for those suffering from pain associated with a muscle or joint injury.

Benefits and Costs

The proposed amendment would impact on the following sectors:

- **Public**

  The availability of diclofenac 1% as a nonprescription product would provide consumers with more convenient access to this topical treatment for muscle or joint injury.

  Product labels would be required to include directions for use and applicable cautionary statements. This would help to provide information to the public about the product's safe and proper use.

  The public would be required to pay directly for the product as products which do not require a prescription are not usually covered by drug insurance plans.

.../3

- **Health Insurance Plans**

  There would be no anticipated cost for privately funded drug benefit plans since most do not cover the cost of nonprescription drugs.

- **Provincial Health Care Services**

  There would be no anticipated cost to provincial drug benefit plans since most do not cover the costs of nonprescription drugs.

Compliance and Enforcement

This amendment would not alter existing compliance mechanisms under the provisions of the *Food and Drugs Act* and the *Food and Drug Regulations* enforced by the Health Products and Food Branch Inspectorate.

Consultation

The process for this consultation with stakholders is described in the Memorandum of Understanding (MOU) to streamline regulatory amendments to Schedule F, which came into effect on February 22, 2005. The MOU is posted on the Health Canada website.

This NOI is being sent by email to stakeholders and is also being posted on the Health Canada website and the *Consulting With Canadians* website.

Any comments regarding this proposed amendment should be sent within **75** days following the date of publication in *Canada Gazette*, Part I. The policy analyst for this project, Karen Ash, may be contacted at:

Refer to Project 1541
Policy Division
Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
1600 Scott Street, Holland Cross
Tower 'B', 2nd Floor
A.L. 3102C5
Ottawa, Ontario K1A 0K9
Telephone: 613-948-4623
Facsimile: 613-941-6458
email: regaff-affreg@hc-sc.gc.ca

Final Approval

In accordance with the MOU process, it is anticipated that this amendment will proceed directly from this consultation to consideration for final approval by the Governor in Council, approximately 6 to 8 months from the date of publication of this NOI in the *Canada Gazette,* Part I. If approved by the Governor in Council, publication in the *Canada Gazette*, Part II, would follow. The amendment will come into force on the date of registration.

Yours sincerely,

Original signed by

Neil Yeates
Assistant Deputy Minister